



## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference W1288-00	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2003/013572	International filing date (day/month/year) 23 October 2003 (23.10.2003)	Priority date (day/month/year) 31 October 2002 (31.10.2002)	
International Patent Classification (IPC) or national classification and IPC G01N 33/566			
Applicant NIHON MEDI-PHYSICS CO., LTD.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>
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Date of submission of the demand 13 February 2004 (13.02.2004)	Date of completion of this report 04 June 2004 (04.06.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/013572

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- international search (under Rules 12.3 and 23.1(b))
  - publication of the international application (under Rule 12.4)
  - international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- The international application as originally filed/furnished
- the description:  
pages \_\_\_\_\_, as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- the claims:  
pages \_\_\_\_\_, as originally filed/furnished  
pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- the drawings:  
pages \_\_\_\_\_, as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/13572

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

## 2. Citations and explanations

Document 1: WO 00/78352 A (Nihon Mediphysics Co., Ltd.),  
 28 December 2000, & EP 1197227 A & CA  
 2376159 A

## Claims 1 to 10

Document 1 cited in the international search report makes disclosures pertaining to a method for measuring the blood plasma albumen-bonding sites of a substance to be measured by reacting the substance to be measured, which has blood plasma albumen-bonding sites to be measured, with a given substance, which has known blood plasma albumen-bonding sites, and measuring the resulting release ratio (refer to the examples and the like). Consequently, claims 1 to 10 do not involve an inventive step in the light of document 1.

## Claims 11 to 17

In general, it is obvious to a person skilled in the art that if a protein is normal, then said protein will exhibit the characteristics that are intrinsic to such a protein, whereas if the protein is abnormal, then said protein will no longer exhibit the characteristics that are intrinsic to such a protein. Consequently, it would be easy for a person skilled in the art to investigate the

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

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bonds between a protein and a given substance that should bond with the protein at specific sites, and to infer that said protein has been mutated in cases when the protein does not bond in the manner that is intrinsic to such a protein.

**Claims 18 to 20**

A person skilled in the art could configure a kit from the reagents that are used in the measurement method in question, as appropriate.